

EXHIBIT 504

Terry Kilpatrick

From: Lapointe, Jon-Paul [JLapointe@eapdlaw.com]
Sent: Tuesday, December 22, 2009 11:21 AM
To: Don A. Ernst; Terry Kilpatrick
Cc: Moriarty, Matthew; Donahue, Alicia J. (SHB); McDonough, Madeleine (SHB); Kaplan, Harvey L. (SHB)
Subject: Digitek--- McCornack

Don,
Attached are a Verification and copies of records CVS received from Mylan/Actavis/UDL concerning the Digitek recall. Pursuant to our discussions, kindly confirm that you are withdrawing the CVS custodian of records deposition scheduled for February 2, 2010.
Regards, Jon-Paul

Jon-Paul Lapointe
Edwards Angell Palmer & Dodge LLP
660 Newport Center Drive, Suite 650
Newport Beach, CA 92660

Direct 949.423.2103
Mobile 401.450.4500
Direct Fax 888.325.9121

www.eapdlaw.com

Boston MA, Ft. Lauderdale FL, Hartford CT, Madison NJ, New York NY, Newport Beach CA, Providence RI, Stamford CT, Washington DC, West Palm Beach FL, Wilmington DE, London UK, Hong Kong (associated office)

CONFIDENTIALITY NOTICE

This e-mail message from Edwards Angell Palmer & Dodge LLP and Edwards Angell Palmer & Dodge UK LLP is intended only for the individual or entity to which it is addressed. This e-mail may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this e-mail by accident, please notify the sender immediately and destroy this e-mail and all copies of it. We take steps to protect against viruses but advise you to carry out your own checks and precautions as we accept no liability for any which remain. We may monitor emails sent to and from our server(s) to ensure regulatory compliance to protect our clients and business.

Edwards Angell Palmer & Dodge UK LLP is a limited liability partnership registered in England (registered number OC333092) and is regulated by the Solicitors Regulation Authority. A list of members' names and their professional qualifications may be inspected at our registered office, One Fetter Lane, London EC4A 1JB, UK, telephone +44 207 583 4055.

Disclosure Under U.S. IRS Circular 230: Edwards Angell Palmer & Dodge LLP informs you that any tax advice contained in this communication, including any attachments, was not intended or written to be used, and cannot be used, for the purpose of avoiding federal tax related penalties or promoting, marketing or recommending to another party any transaction or matter addressed herein.

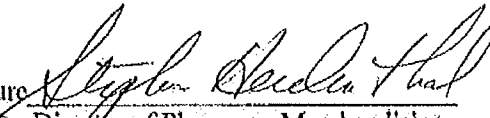
12/22/2009

PLAINTIFFS' EXHIBITS 001191

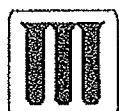
VERIFICATION

I hereby declare that the following statements are true and correct and based upon my personal knowledge. I am an employee of CVS Caremark Corporation ("CVS"). I am familiar with the Digitek recall in 2008. I hereby certify that the records produced herewith are true and accurate copies of all of the records CVS received from Mylan Pharmaceuticals and/or Actavis Totowa concerning the Digitek recall.

Name STEPHEN HEIDENTHAL

Signature 
Director of Pharmacy Merchandising

Date 12/15/09



MYLAN®

Mylan Pharmaceuticals Inc.

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
PO Box 4310
Morgantown, WV 26504-4310

Federal ID 55-0455423
Remittance Only :
PO Box 72504
Cleveland, OH 44192-0504

Sold To: 300049
CVS Distribution, Inc.
P.O. Box 3120
Accounts Payable Dept. V-4970
Woonsocket RI 02895

Credit Memo 1600019492

Date : 08/08/2008
Reference : MYL72308

DESCRIPTION	AMOUNT
Digitek Recall Fee	2,233,781.00
Total	USD 2,233,781.00

Disclaimer: This invoice reflects a discounted price, credit or rebate and/or price reduction earned and paid with respect to the products described herein. Federal law requires disclosure on the price reduction on your claim or cost reports for Medicare or Medicaid reimbursement under 42 U.S.C 1320(A)-7B.

Heldenthal, Stephen E.

From: Hinson, Andy
Sent: Monday, April 28, 2008 10:46 AM
To: Heldenthal, Stephen E.
Subject: RE: text Actavis press release

Per Stericycle this is all on the affected NDC's. It's just the Mylan Bortex products.

- 1). Digitek 0.125mcg 100 ct 62794-0145-01
- 2). Digitek 0.125mcg 1,000 ct 62794-0145-10
- 3). Digitek 0.125mcg 5,000 ct 62794-0145-56
- 4) Digitek 0.25mcg 100 ct 62794-0146-01
- 6). Digitek 0.25 mcg 1,000 ct 62794-0146-10
- 8). Digitek 0.25mcg 5,000 ct 62794-0146-56

*per
Stericycle*

Andy Hinson

Quality Technician

CVS Caremark

2211 Sanders Road NBT 6

Northbrook, IL 60062

Phone # 847-559-3790

Fax # 847-559-5779

From: Heldenthal, Stephen E.
Sent: Monday, April 28, 2008 8:41 AM
To: Hinson, Andy
Subject: FW: text Actavis press release
Importance: High

Andy -

Class I - not on FDA site yet this AM.

4/28/2008

Please forward copy of patient letter and communications once developed

Thanks
Steve

From: Shea, Mike J. (RX Merch)
Sent: Monday, April 28, 2008 9:20 AM
To: Heldenthal, Stephen E.
Subject: FW: text Actavis press release

From: Ann.Wolfe@mylan.com [mailto:Ann.Wolfe@mylan.com]
Sent: Monday, April 28, 2008 9:17 AM
To: Shea, Mike J. (RX Merch)
Cc: Bob.Potter@mylanlabs.com
Subject: Fw: text Actavis press release

Mike,

Good morning, Mr. Bob Potter ask that I forward a copy of the Actavis Recall Press Release. Thank you.

Press releases

25.04.2008 / Product

Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek (digoxin tablets, USP) as a precaution

Morristown, NJ, 25 April, 2008 - Actavis Totowa LLC, a United States manufacturing division of the International generic pharmaceutical company Actavis Group, is initiating a Class 1 nationwide recall of Digitek (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals, Inc. under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all-lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.

Digitek is used to treat heart failure and abnormal heart rhythms. The existence of double-strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illness and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6166 with representatives available Monday through Friday, 8 am to 5 pm EST. Additional information about the voluntary recall can also be found at www.actavis.us.

4/28/2008

Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Ann Wolfe
Executive Director, Sales Support & Customer Relations
800.796.9526 x5648

CONFIDENTIALITY NOTICE: This e-mail message and all attachments transmitted with it may contain
CONFIDENTIAL INFORMATION

4/28/2008

Heldenthal, Stephen E.

- Save -

From: Shea, Mike J. (RX Merch)
Sent: Monday, April 28, 2008 6:40 PM
To: Heldenthal, Stephen E.; Heneghan, Craig P.
Subject: FW: 4.28.08 Digitek Recall Letter
Attachments: Actavis Press Release 4.25.08_v2.pdf; Recall notification letter from Stericycle_0001.pdf

From: Ann.Wolfe@mylan.com [mailto:Ann.Wolfe@mylan.com]
Sent: Monday, April 28, 2008 6:43 PM
To: Shea, Mike J. (RX Merch)
Cc: Bob.Potter@mylanlabs.com
Subject: Fw: 4.28.08 Digitek Recall Letter

This email is to inform you there has been an Actavis press release (see below) pertaining to the recall of Digitek® (Digoxin Tablets, USP). The contracting agency handling the logistics of the recall is as follows:

STERICYLCE CUSTOMER SERVICE
1.888.276.6166

For your convenience, attached is a copy of the notification letter that will be sent by Stericycle as early as tonight. Please be advised thereafter you will also receive the same letter directly from Stericycle, along with a business reply card and packing slip as referenced in the attached letter. In essence you will receive the official letter from Stericycle regarding the logistics of the recall.

We appreciate your immediate attention to this important matter and sincerely regret any inconvenience caused by this action.
Thank you.

Ann Wolfe
Executive Director, Sales Support & Customer Relations
800.796.9626

CONFIDENTIALITY NOTICE: This e-mail message and all attachments transmitted with it may contain
=====

4/28/2008

PRESS : NEWSROOM : ARTICLES

PRESS RELEASES

25.04.2008 / Product

Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek (digoxin tablets, USP) as a precaution

Morristown, NJ, 25 April, 2008 - Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class 1 nationwide recall of Digitek (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals, Inc. under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all-lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.

Digitek is used to treat heart failure and abnormal heart rhythms. The existence of double-strength tablets poses a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitek intake. Several reports of illness and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6106 with representatives available Monday through Friday, 8 am to 6 pm EST. Additional information about the voluntary recall can also be found at www.actavis.us.

Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-0787, or on the MedWatch website at www.fda.gov/medwatch.

<http://www.actavis.us/en/media+center/newsroom/articles/digitek+recall.htm>

4/25/2008

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

Recall initiated by the manufacturer: Actavis Totowa LLC (formerly known as Amide Pharmaceuticals, Inc.)
Product Distributed by: Mylan Pharmaceuticals, Inc. under a "Bertek" Label

PRODUCT	NDC	Name	Strength	Size	Lot #
	62794-145-01	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 100s	All lots
	62794-145-10	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 1000s	All lots
	62794-145-56	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 5000s	All lots
	62794-146-01	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 100s	All lots
	62794-146-10	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 1000s	All lots
	62794-146-56	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 5000s	All lots

REASON Mylan Pharmaceuticals Inc. is continuing a voluntary recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP). This product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate. Product was distributed nationwide between March 2006 and April 2008.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received by Actavis.

ACTION

1. Immediately examine your inventory and quarantine and discontinue distribution of all lots within expiry.
2. In addition, if you may have further distributed the recalled product, please identify your retail-level customers and notify them at once of this product recall.
3. Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall. They should instruct the consumer to contact Stericycle at 1-888-276-6166 for the return of the product.
4. Consumers should discuss their treatment options and change in therapy with their physician.
5. Carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter. Federal Regulations require a physical count.
6. Mail the postage paid Business Reply Card to the address provided. Federal regulations require that you return this completed card even if you do not have the recalled product.
7. Return the recalled product with the Packing Slip using the prepaid UPS Authorized Return Service shipping labels to:
Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241

OTHER This recall extends to the consumer level.

Credit/check will be issued for return of recalled product.

Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.

For questions regarding Digitek® Tablets (digoxin tablets, USP) recall, please call Stericycle at 1-888-276-6166

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Shea, Mike J. (RX Merch)

From: Ann.Wolfe@mylan.com
Sent: Monday, April 28, 2008 1:30 PM
To: Shea, Mike J. (RX Merch)
Cc: Ashley.Vitale@mylanlabs.com; Bob.Potter@mylanlabs.com; Heldenthal, Stephen E.
Subject: Re: Important Questions- Digitek Recall

Below is the NDC list of Digitek Product that was shipped to either CVS or Caremark:

<u>NDC</u>	<u>Product</u>
62794-145-01	Digitek 0.125 mg 100s
62794-145-56	Digitek 0.125 mg 5000s
62794-146-01	Digitek 0.25 mg 100s
62794-146-56	Digitek 0.25 mg 5000s

The recall goes back to 03.01.08, in essence 24 months - shelf life of product. The earliest product involved in the recall shipped to both CVS and Caremark is actually 03.01.08. Please let me know if you need any additional information pertaining to this matter.

Ann Wolfe
Executive Director, Sales Support & Customer Relations
800.796.9526

"Shea, Mike J. (RX Merch)" <MJShea@cvs.com>

To: Bob.Potter@mylanlabs.com, Ashley.Vitale@mylanlabs.com,
Ann.Wolfe@mylan.com

04/28/2008 11:44 AM

cc: "Heldenthal, Stephen E." <SEHeldenthal@cvs.com>
Subject: Important Questions- Digitek Recall

Bob

Please provide the following information ASAP

- 1) Actual NDC list impacted by the Class One Voluntary Digitek Recall
- 2) Earliest Date affected product (all lots) were shipped into trade

Thanks
Mike

=====

CONFIDENTIALITY NOTICE: This e-mail message and all attachments transmitted with it

=====

4/28/2008

Heldenthal, Stephen E.

From: Ann.Wolfe@mylan.com
Sent: Tuesday, April 29, 2008 10:32 AM
To: Shea, Mike J. (RX Merch)
Cc: Bob.Potter@mylanlabs.com; Heldenthal, Stephen E.; Ashley.Vitale@mylanlabs.com
Subject: copies of Digitek labels
Attachments: 945-20.pdf; 945-56.pdf; 945-66.pdf; 946-20.pdf; 946-66.pdf; Digitek label Bertek.pdf

Mike,

Below are copies of digitek labels:

Please let me know if you need any additional information. Thank you.

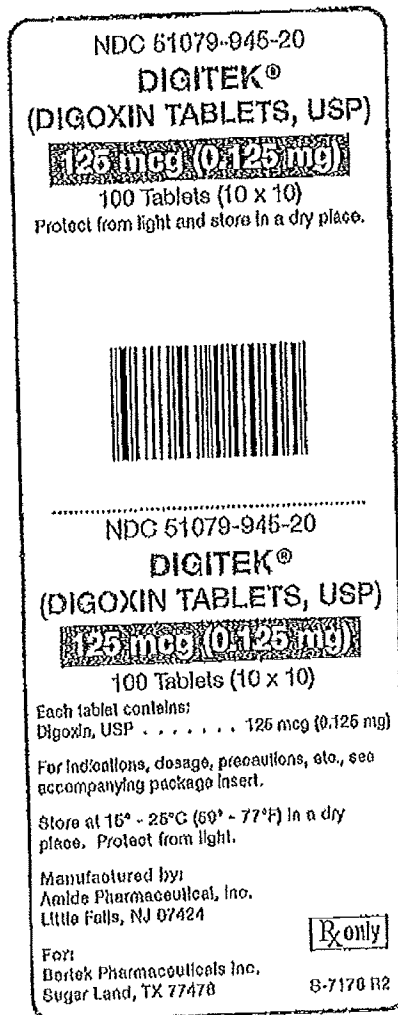
Ann Wolfe

=====

CONFIDENTIALITY NOTICE: This e-mail message and all attachments transmitted with it may contain

=====

4/30/2008



NDC 51079-945-56
DIGITEK®
(DIGOXIN TABLETS, USP)
125 mcg (0.125 mg)
300 Tablets (10 x 30)
Protect from light and store in a dry place.

NDC 51079-945-56


DIGITEK®
(DIGOXIN TABLETS, USP)
125 mcg (0.125 mg)
300 Tablets (10 x 30)

Each tablet contains:
Digoxin, USP 125 mcg (0.125 mg)

For indications, dosage, precautions, etc.,
see accompanying package insert.

Store at 15° - 25°C (59° - 77°F) in a dry
place. Protect from light.

Manufactured by:
Amide Pharmaceuticals, Inc.
Little Falls, NJ 07424

For: 
Bertek Pharmaceuticals Inc.
Sugar Land, TX 77478 S-9831

Rx only

NDC 51079-945-66

DIGITEK® (DIGOXIN TABLETS, USP)

125 mcg (0.125 mg)

180 Tablets (6 x 30)

Each tablet contains: Digoxin, USP 125 mcg (0.125 mg)

For indications, dosage, precautions, etc., see accompanying package insert.

Store at 15° - 25°C (59° - 77°F) in a dry place. Protect from light.

Keep this and all drugs out of the reach of children.

Manufactured by:
Amide Pharmaceuticals, Inc.
Little Falls, NJ 07424

NDC 51079-945-66

DIGITEK®

(DIGOXIN TABLETS, USP)

125 mcg (0.125 mg)

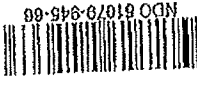
180 Tablets (6 x 30)

Protect from light and store in a dry place.

Lot No.: 7P964

Exp. Date: 4/09

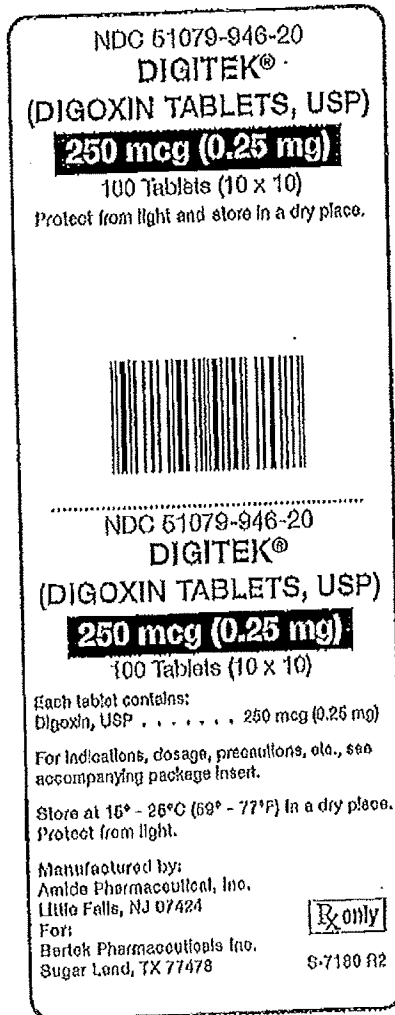
S-9765



NDC 51079-945-66

2/Kg and Distributed by:
UDL Laboratories, Inc.
Rockford, IL 61103

For:
Berk Pharmaceuticals Inc.
Sugar Land, TX 77478



Roche

NDC 51079-946-66

DIGITEK® (DIGOXIN TABLETS, USP)

250 mcg (0.25 mg)

180 Tablets (6 x 30)

Each tablet contains: Digoxin, USP 250 mcg (0.25 mg)

For indications, dosage, precautions, etc., see accompanying package insert.

Store at 15° - 25°C (59° - 77°F) in a dry place. Protect from light.

Keep this and all drugs out of the reach of children.

Manufactured by:
Amide Pharmaceuticals, Inc.
Little Falls, NJ 07424

NDC 51079-946-66

DIGITEK®

(DIGOXIN TABLETS, USP)


250 mcg (0.25 mg)

180 Tablets (6 x 30)

Protect from light and store in a dry place.

Lot No.: 8A5582

Exp. Date: 7/09 S-8757 R1



NDC 51079-946-66

PKG and Distributed by:
UDI Laboratories, Inc.
Rockford, IL 61103

For:
Berkel Pharmaceuticals Inc.
Sugar Land, TX 77478

Ref: 10/1/10

NDC 62794-146-01

DIGITEX

(digoxin tablets, USP)

250 mcg (0.25 mg)

180 TABLETS

Rx only


Each tablet contains:
Digoxin, USP 250 mcg (0.25 mg)

For indications, dosage, precautions,
etc., see accompanying package insert.

Dispense in a tight, light-resistant
container as defined in the USP.

Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.

This is a bulk container and not
intended for dispensing for household
use.



62794-146-01 3

Distributed by
BERTEK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.:
Exp. Date:
8057-01

RBK146A1

Labelled

NDC 62794-146-56

DIGITEX

(digoxin tablets, USP)

250 mcg (0.25 mg)

5000 TABLETS

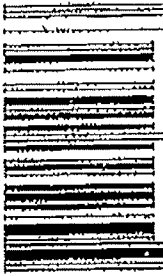
Rx only

Each tablet contains:
Digoxin, USP 250 mcg (0.25 mg)
For indications, dosage, precautions,
etc., see accompanying package
insert.

Dispense in a tight, light-resistant
container as defined in the USP.

Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.

This is a bulk container and not
intended for dispensing for household
use.



N 62794-146-56 3

Distributed by
BERTHEK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.:
Exp. Date:
6069-01

RSK14521

NDC 62794-146-10

DIGITEL

(digoxin tablets, USP)

250 mcg (0.25 mg)

1000 TABLETS

Rx only


Each tablet contains:
Digoxin, USP 250 mcg (0.25 mg)

For indications, dosage, precautions, etc.,
see accompanying package insert.

Dispense in a light, light-resistant container
as defined in the USP.

Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.

This is a bulk container and not intended
for dispensing for household use.



N 62794-146-10 5

Manufactured by
BERTHEK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.:
Exp. Date:
8068-01

RBK146C1

Lot/Exp
2D

NDC 62794-145-01

DIGITEL

(digoxin tablets, USP)

125 mcg (0.125 mg)

100 TABLETS

Rx only


Each tablet contains:
Digoxin, USP 125 mcg (0.125 mg)

For indications, dosage, precautions,
etc., see accompanying package insert.

Dispense in a tight, light-resistant
container as defined in the USP.

Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.

This is a bulk container and not
intended for dispensing for household
use.



3 62794-145-01 6

Distributed by
BERTERK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.:
Exp. Date:
8064-01

FSK145A1

09/12/01

NDC 62794-145-10

DIGITEK

(digoxin tablets, USP)

125 mg (0.125 mg)


1000 TABLETS

Rx only

Each tablet contains:
Digoxin, USP 125 mcg (0.125 mg)
For indications, dosage, precautions, etc.,
see accompanying package insert.
Dispense in a tight, light-resistant container
as defined in the USP.
Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.
This is a bulk container and not intended
for dispensing for household use.

Control No.:
Exp. Date:
8085-01

FBK145C1



N 62794-145-10 8

Distributed by
BERTER PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA
Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

NDG 62794-145-56

DIGITEK

(digoxin tablets, USP)

125 mcg (0.125 mg)

5000 TABLETS

Rx only

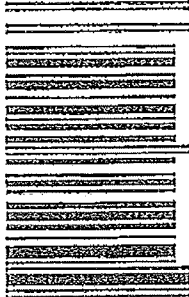
Each tablet contains:
Digoxin, USP . . . 125 mcg (0.125 mg)

For indications, dosage, precautions,
etc., see accompanying package
insert.

Dispense in a tight, light-resistant
container as defined in the USP.

Store at 15°-25°C (59°-77°F) in a dry
place and protect from light.

This is a bulk container and not
intended for dispensing for household
use.



N 3 62794-145-56 6

Distributed by
BERTEK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.:
Exp. Date:
8056-01

RBK14521

Shea, Jessica

From: Shea, Mike J. (RX Merch)
Sent: Tuesday, April 29, 2008 1:47 PM
To: Heldenenthal, Stephen E.; Shea, Jessica
Subject: FW: UDL Copy of Digitek Recall Letter
Attachments: Actavis Press Release 4.26.08_v2.pdf; UDL Digitek Recall Letter 042808.pdf

lyl

From: Ann.Wolfe@mylan.com [mailto:Ann.Wolfe@mylan.com]
Sent: Tuesday, April 29, 2008 12:59 PM
To: undisclosed-recipients
Subject: UDL Copy of Digitek Recall Letter

This email is to inform you there has been an Actavis press release (see below) pertaining to the recall of Digitek® (Digoxin Tablets, USP). The contracting agency handling the logistics of the recall is as follows:

STERICYCLE CUSTOMER SERVICE
1.888.473.8015

For your convenience, attached is a copy of the notification letter that will be sent by Stericycle. Please be advised thereafter you will also receive the same letter directly from Stericycle, along with a business reply card and packing slip as referenced in the attached letter. In essence you will receive the official letter from Stericycle regarding the logistics of the recall.

We appreciate your immediate attention to this important matter and sincerely regret any inconvenience caused by this action. Thank you.

Ann Wolfe
Executive Director, Sales Support & Customer Relations
800.796.9526 x5648

=====

CONFIDENTIALITY NOTICE: This e-mail message and all attachments transmitted with it

=====

5/8/2008

PRESS : NEWSROOM : ARTICLES

PRESS RELEASES

25.04.2008 / Product

Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek (digoxin tablets, USP) as a precaution

Morrisown, NJ, 25 April, 2008 - Actavis Totowa LLC, a United States manufacturing division of the International generic pharmaceutical company Actavis Group, is initiating a Class 1 nationwide recall of Digitek (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals, Inc. under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all-lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.

Digitek is used to treat heart failure and abnormal heart rhythms. The existence of double-strength tablets poses a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitek intake. Several reports of illness and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6166 with representatives available Monday through Friday, 8 am to 5 pm EST. Additional information about the voluntary recall can also be found at www.actavis.us.

Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 6600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

<http://www.actavis.us/en/media+center/newsroom/articles/digitek+recall.htm>

4/25/2008



UDL LABORATORIES, INC.

Urgent: Drug Recall
Digitek® (digoxin tablets, USP)
ALL LOTS WITHIN EXPIRY

Recall initiated by the manufacturer: Actavis Totowa LLC
(formerly known as Amide Pharmaceutical, Inc.)

Product Distributed by: UDL Laboratories, Inc. under a "UDL" Label

April 28, 2008

RE: Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: UD100 (10 x 10)
NDC 51079-945-20
Lots: 7A666 (Exp. 7/08); 7F048 (Exp. 10/08); 7D352 (Exp. 12/08); 7P862 (Exp. 3/09)
8C515 (Exp. 9/09)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: UD300 (10 x 30)
NDC 51079-945-57
Lot: 6S406 (Exp. 5/08)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: PC300 (10 x 30)
NDC 51079-945-56
Lot: 7J541 (Exp. 1/09); 7M709 (Exp. 3/09); 7P965 (Exp. 4/09); 8A266 (Exp. 7/09);
8C514 (Exp. 9/09)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: CP180 (6 x 30) Compliance Package
NDC 51079-945-66
Lot: 7P964 (Exp. 4/09); 8B371 (Exp. 8/09)

Digitek® (Digoxin Tablets, USP) 250 mcg (0.25 mg)
Package Size: UD100 (10 x 10)
NDC 51079-946-20
Lots: 6S379 (Exp. 5/08); 7C971 (Exp. 9/08); 7J525 (Exp. 1/09); 7V200 (Exp. 6/09)

Digitek® (Digoxin Tablets, USP) 250 mcg (0.25 mg)
Package Size: CP180 (6 x 30) Compliance Package
NDC 51079-946-66
Lot: 7P963 (Exp. 4/09); 8A332 (Exp. 7/09)

1864_0101AD

Dear Customer:

UDL is continuing a voluntary Class I nationwide recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP, all strengths). This product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake.

THIS RECALL IS BEING CONDUCTED TO THE CONSUMER LEVEL.

If you are in possession of any of the recalled lots, quarantine and discontinue distributing, dispensing or taking this product immediately. If you have further distributed this recalled product, please identify your retail-level customers and notify them at once of this recall. Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall. They should instruct the consumer to contact Stericycle at 1-888-473-8015. Consumers should discuss their treatment options and change in therapy with their physician. Several reports of illnesses and injuries have been received by Actavis.

Please examine your stock, carry out a physical count and record this data on the attached Business Reply Card and Packing Slip. Federal Regulations require a physical count. Federal Regulations also require that you return a completed Business Reply Card even if you do not have the recalled product. Return the Business Reply Card to the address provided. If you have inventory, promptly return the product using the prepaid UPS Authorized Return Service shipping labels to:

Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241

ATTN: UDL Digitek® Recall

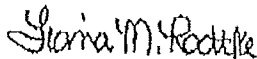
Credit will be issued for return of recalled product only.

For questions regarding the processing of the Digitek® Tablets (digoxin tablets, USP) recall, please call Stericycle at 1-888-473-8015.

Any adverse reaction experiences with the use of this product, and/or quality problems should also be reported to the FDA MedWatch Program by telephone at 1-800-FDA-1088 or on the MedWatch website at www.fda.gov/medwatch. Also contact Actavis at 1-800-432-8534.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Sincerely,



LJANA M. RADTKE
Senior Director Regulatory Affairs/Compliance

1864_0101BD